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Medical electrical equipment —

Part 2-58:
Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

Appareils électromédicaux —

Partie 2-58:
Exigences particulières pour la sécurité de base et les performances essentielles des dispositifs de retrait du cristallin et des dispositifs de vitrectomie pour la chirurgie ophtalmique

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

FOREWORD

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International standard IEC 80601-2-58 has been prepared by subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and subcommittee SC 7: Ophthalmic optics and instruments of ISO technical committee 172: Optics and photonics.

This second edition cancels and replaces the first edition of IEC 80601-2-58 published in 2008.

It is published as a double logo standard.

The text of this standard is based on the following documents:

FDIS	Report on voting
62D/1151/FDIS	62D/1161/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 12 P members out of 12 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or”, so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title *Medical electrical equipment,* can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

INTRODUCTION

LENS REMOVAL DEVICES and VITRECTOMY DEVICES are used widely in ophthalmology to perform anterior-segment and posterior-segment surgery on the human eye. Commercial use of these MEDICAL ELECTRICAL EQUIPMENT devices began in the early 1970s. This International Standard defines particular requirements for BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES, comprising an equipment console, surgical HANDPIECES and ACCESSORIES connected to this ME EQUIPMENT.

In many parts of the world LENS REMOVAL DEVICES and VITRECTOMY DEVICES are used in combination by ophthalmic surgeons to perform combined anterior-segment (lens removal) and posterior-segment (vitreoretinal) surgical PROCEDURES to maximize surgical outcomes. For this reason both LENS REMOVAL DEVICES and VITRECTOMY DEVICES are covered in this International Standard.

As all particular standards in the IEC 60601-1 series are based on the general standard IEC 60601-1, the user of this standard is reminded that RISK MANGEMENT plays an important role in the use of this particular standard. Compliance with the requirements of this particular standard should be documented in the RISK MANAGEMENT FILE to ensure the HAZARDS associated with the product have been considered fully.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

201.1 Scope, object and related standards

Clause 1 of the general standard[1] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.208 and 201.3.217) and associated ACCESSORIES that can be connected to this MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

HAZARDS inherent in the intended physiological function of ME EQUIPMENT or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of the general standard.

NOTE See also 4.2 of the general standard.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for LENS REMOVAL DEVICES and VITRECTOMY DEVICES for ophthalmic surgery (as defined in 201.3.208 and 201.3.217) and associated ACCESSORIES that can be connected to the ME EQUIPMENT and are to be tested together or individually.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this particular standard.

IEC 60601-1-2:2007 applies as modified in Clause 202. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

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[1] The general standard is IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the “general standard”. Collateral standards are referred to by their document number.

The numbering of clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where × is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

”Replacement” means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

“Addition” means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

“Amendment” means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses, figures or tables which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses, figures or tables which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term “this standard” is used to make reference to the general standard, any applicable collateral standard and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 26.

Clause 2 of the general standard applies, except as follows:

Replacement:

IEC 60601-1-2:2007[2], *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests*

Addition:

IEC 60601-2-2, *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*

IEC 60601-2-22, *Medical electrical equipment – Part 2-22: Particular requirements for the basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment*

ISO 11607-1:2006, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11607-2:2006, *Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes*

ISO 17664:2004, *Sterilization of medical devices – Information to be provided by the manufacturer for the processing of resterilizable medical devices*

201.3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1, apply, except as follows:

NOTE An index of defined terms is found beginning on page 27.

Addition:

201.3.201
ASPIRATION
drawing fluid or gas out of the eye by use of suction

201.3.202
DIATHERMY
surgical technique using high frequency (HF) electrical currents to stop bleeding in tissue

Note 1 to entry: Diathermy is used, for example, to coagulate blood or bind tissues together.

Note 2 to entry: The terms “cautery” or “coagulation” have also been used in this context.

201.3.203
DRAIN CONTAINER
sealed container (or bag) in which aspirated fluid is collected

201.3.204
HANDPIECE
PROBE
handheld APPLIED PART, an ACCESSORY of LENS REMOVAL DEVICES or VITRECTOMY DEVICES

[2] Third edition. Although a new, fourth edition of IEC 60601-1-2 was published in 2014, the normative references to this collateral standard in the present particular standard refer to the third edition, published in 2007.

201.3.205
LASER
any device which can be made to produce or amplify electromagnetic radiation in the wavelength range from 180 nm to 1 mm primarily by the process of controlled stimulated emission

[SOURCE: IEC 60825-1:2007, 3.41]

201.3.206
LASER FRAGMENTATION
method by which the lens is broken into small fragments using LASER energy

201.3.207
LENS REMOVAL
removal of unwanted lens tissue

201.3.208
LENS REMOVAL DEVICE
ME EQUIPMENT or ME SYSTEM designed to remove lens material which incorporates an IRRIGATION and ASPIRATION function, and a mechanism for LENS REMOVAL such as PHACOEMULSIFICATION, LIQUEFACTION, or LASER FRAGMENTATION

Note 1 to entry: These devices may also be used for other ocular surgical purposes.

201.3.209
LIQUEFACTION FRAGMENTATION
LIQUEFACTION
method by which the lens is broken into small fragments by means of pulses of ophthalmic IRRIGATION solution

201.3.210
OCULAR IRRIGATION
IRRIGATION
introduction of a liquid into the eye

Note 1 to entry: The term “infusion” has also been used in this context

201.3.211
PHACOFRAGMENTATION
method by which the lens is broken into small fragments using energy such as from ultrasonic devices

Note 1 to entry: Refer to the definition of LENS REMOVAL DEVICE in 201.3.208.

Note 2 to entry: Historically PHACOFRAGMENTATION (term is also identified as phacoemulsification) has been a surgical PROCEDURE that uses ultrasonic energy to fragment (or emulsify) a cataractous lens and removes the lens material through a small incision. Recently, other emerging energy modalities, including LASER FRAGMENTATION and LIQUEFACTION, have also been utilized in the removal of the cataractous lens through a small incision.

201.3.212
PHOTORETINITIS
retinal injury resulting from a very intense retinal radiant exposure

201.3.213
PRIME
PRIMING
pre-operative setup PROCEDURE to fill TUBING SET (fluid path) with ophthalmic IRRIGATION solution

201.3.214
TIP
hollow needle-like device that is attached to a HANDPIECE

201.3.215
TUBING SET
set of tubes to contain fluid, designed to provide IRRIGATION to the eye and ASPIRATION from the eye

201.3.216
VITRECTOMY
surgical PROCEDURE to remove vitreous humour, membranes, blood, lens tissue and other material from the eye, involving IRRIGATION, ASPIRATION and vitreous cutting

Note 1 to entry: The PROCEDURE may also include illumination, DIATHERMY, fluid/gas exchanges, and injection of viscous fluids.

201.3.217
VITRECTOMY DEVICE
ME EQUIPMENT or ME SYSTEM used to perform VITRECTOMY

Note 1 to entry: These devices may also be used for other ocular surgical purposes.

201.4 General requirements

Clause 4 of the general standard applies, except as follows:

201.4.3 * ESSENTIAL PERFORMANCE

Addition:

201.4.3.101 General

For LENS REMOVAL DEVICES and VITRECTOMY DEVICES no ESSENTIAL PERFORMANCE has been identified in general. If the LENS REMOVAL DEVICES and VITRECTOMY DEVICES have functions other than those specified in Clause 201.12, the MANUFACTURER shall identify which of these functions of the ME EQUIPMENT and ME SYSTEMS is ESSENTIAL PERFORMANCE.

Compliance is checked by inspection of the RISK MANAGEMENT FILE.

Addition:

201.4.101 * Additional functions

If there is a DIATHERMY function used for the LENS REMOVAL DEVICE and VITRECTOMY DEVICE, that function shall meet the requirements of IEC 60601-2-2.

If the ME EQUIPMENT includes a LASER function, that function shall meet the requirements of IEC 60601-2-22.

If there is an illumination function used to illuminate the eye during surgery that is part of the ME EQUIPMENT or ME SYSTEM, then that portion of the ME EQUIPMENT or ME SYSTEM shall meet 201.12.4.101.5.

201.5 General requirements for testing of ME EQUIPMENT

Clause 5 of the general standard applies.

201.6 Classification of ME EQUIPMENT and ME SYSTEMS

Clause 6 of the general standard applies.

201.7 ME EQUIPMENT identification, marking and documents

Clause 7 of the general standard applies, except as follows:

201.7.9.2.2 Warning and safety notices

Addition:

The instructions for use shall additionally include the following warning and safety notices:

a) a warning to use only recommended TUBING SET(s);

b) if an electrically adjustable ophthalmic IRRIGATION solution support pole is used, a warning not to modify pole height or manually force the pole height because this could cause incorrect indication of bottle height and PATIENT injury;

c) a warning never to intentionally modify HANDPIECES or TIPS (e.g. do not bend, cut, or engrave them) as they could break or malfunction;

d) a warning to the OPERATOR not to touch an activated ultrasonic HANDPIECE TIP, as injuries could occur;

e) if applicable, warnings related to lamp replacement (e.g. RISK of injury, ratings of lamp, damage to lamp, damage to machine, etc.);

f) if applicable, a warning to the OPERATOR that care should be taken to avoid concentrating the output of an illumination module on a small area of the retina for unnecessarily prolonged periods of time due to the potential for PHOTORETINITIS and serious permanent PATIENT injury;

g) if applicable, a warning to the OPERATOR that inadvertent activation of functions that are intended for PRIMING or tuning HANDPIECES while the HANDPIECE is in the eye can create a HAZARDOUS SITUATION that could result in PATIENT injury;

h) where gravity is relevant to performance, the ophthalmic IRRIGATION solution source shall be at or above the PATIENT's eye level;

i) a warning to the OPERATOR to ensure sufficient volume of IRRIGATION solution for the PROCEDURE. The level should be monitored during the PROCEDURE;

j) if applicable, a warning to the OPERATOR to ensure that the maximum capacity of the DRAIN CONTAINER is not exceeded as this could cause a HAZARDOUS SITUATION to the PATIENT.

201.7.9.2.8 Start-up PROCEDURE

Addition:

The instructions for use shall include instructions to perform functional checks of the system before first use of the day.

201.7.9.2.9 Operating instructions

Addition:

The operating instructions shall additionally include:

a) if applicable, instructions regarding loading, PRIMING, changing, and reloading the TUBING SET(s), and the TUBING SET(s) change interval to maintain the specified performance;

b) if applicable, instructions regarding the use of clamps on a TUBING SET, the avoidance of ophthalmic IRRIGATION solution free flow conditions, and the PROCEDURE to be followed when changing the ophthalmic IRRIGATION solution source;

c) instructions regarding securely attaching plugs, HANDPIECE cables and other connectors.

201.7.9.2.12 Cleaning, disinfection, and sterilization

Addition:

For parts that are resterilizable, the information for processing shall be in accordance with ISO 17664:2004. This information shall be provided to the RESPONSIBLE ORGANIZATION or the OPERATOR.

201.7.9.2.13 Maintenance

Addition:

The instructions for use shall provide the OPERATOR or RESPONSIBLE ORGANIZATION with a recommendation to inspect all HANDPIECE cables and any cords on a regular basis and a recommendation as to the action to take if damage (e.g. exposed wire, nicks in the insulation, deformation, etc.) is observed.

201.8 Protection against electrical HAZARDS from ME EQUIPMENT

Clause 8 of the general standard applies.

201.9 Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS

Clause 9 of the general standard applies.

201.10 Protection against unwanted and excessive radiation HAZARDS

Clause 10 of the general standard applies.

201.11 Protection against excessive temperatures and other HAZARDS

Clause 11 of the general standard applies, except as follows:

201.11.1.2 Temperature of APPLIED PARTS

201.11.1.2.1 APPLIED PARTS intended to supply heat to a PATIENT

Replacement:

HANDPIECES for DIATHERMY, PHACOFRAGMENTATION, LASER and LIQUEFACTION are considered to be APPLIED PARTS intended to supply heat to a PATIENT.

The temperature or clinical effects shall be determined and documented in the RISK MANAGEMENT FILE.

201.11.6.7 Sterilization of ME EQUIPMENT and ME SYSTEMS

Addition:

The packaging for terminally sterilized ACCESSORIES for LENS REMOVAL DEVICES and VITRECTOMY DEVICES shall comply with the requirements of ISO 11607-1:2006. Validation requirements for forming, sealing, and assembly processes for this packaging shall be consistent with ISO 11607-2:2006.

201.12 Accuracy of controls and instruments and protection against hazardous outputs

Clause 12 of the general standard applies, except as follows:

201.12.1 Accuracy of controls and instruments

Addition:

201.12.1.101 Additional accuracy of controls and instruments requirements

NOTE Additional requirements for accuracy of controls and instruments are detailed in subclauses 201.12.1.101.1 to 201.12.1.101.5 and 201.12.1.101.7 to 201.12.1.101.9.

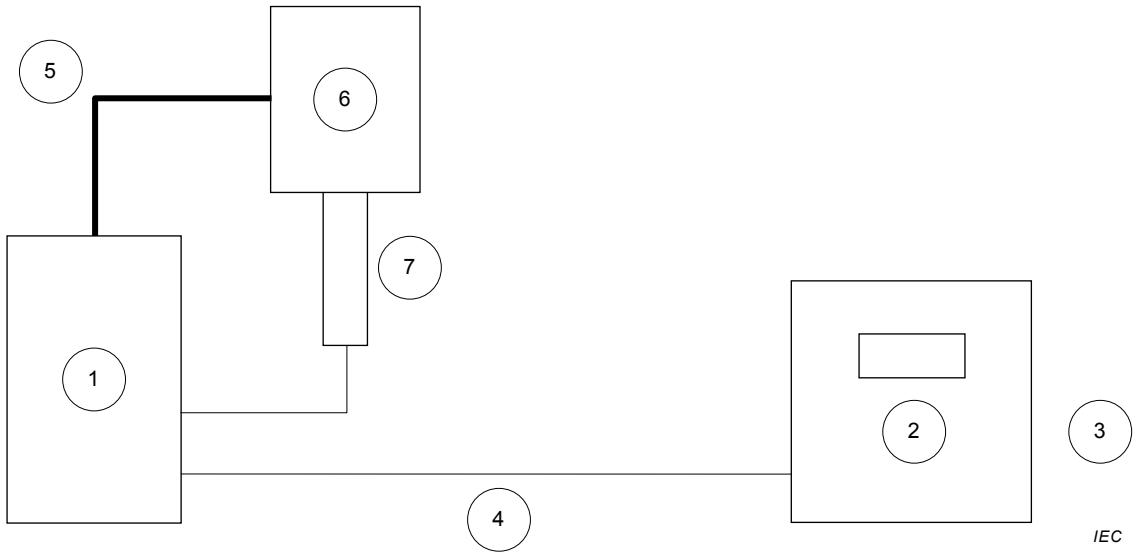
201.12.1.101.1 Accuracy of static IRRIGATION pressure

Static IRRIGATION pressure output shall not deviate from the indicated setting on the LENS REMOVAL DEVICES and VITRECTOMY DEVICES by more than ± 20 % or ± 10 mmHg (± 1,3 kPa) whichever is greater for a specific device in a defined configuration (see 201.12.4.101.1 for hazardous output limit).

Compliance is checked by applying the relevant test method(s) 1 and/or 2:

a) *Test method 1 (Gravity fed IRRIGATION)*

   1) *Set the test environment temperature to 25 °C ± 5 °C.*
   2) *Install the TUBING SET(S) AND PRIME THE DEVICE IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS FOR USE.*
   3) *Zero the pressure meter reading. Connect the pressure meter to the end of the IRRIGATION tubing and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.101.*
   4) *Initiate the flow of fluid in accordance with the MANUFACTURER's instructions for use.*
   5) *Set the gravity feed reservoir height to 0 cm or the lowest setting and record the pressure meter reading after 5 s.*
   6) *Increase the reservoir height by 20 cm and wait for 5 s and record the pressure meter reading.*
   7) *Repeat step 6 until the maximum reservoir height is reached.*
   8) *Record the pressure meter reading at the maximum reservoir height.*
   9) *Repeat the readings at the heights used in steps 5, 6 and 7 as the height is decreased and wait for 5 s and record the pressure meter reading at each point.*
   10) *Confirm that all the readings are within the stated range.*



For key, see Table 201.101

Figure 201.101 – Test method for gravity fed IRRIGATION

b) Test method 2 (pressurized IRRIGATION)

1) Set the test environment temperature to 25 °C ± 5 °C.

2) Install the TUBING SET(S) AND PRIME THE DEVICE IN ACCORDANCE WITH THE MANUFACTURER'S INSTRUCTIONS FOR USE.

3) Zero the pressure meter (PM) reading. Connect the pressure meter to the end of the IRRIGATION TUBING and position the pressure meter within ± 2,5 cm of the simulated PATIENT eye level, see Figure 201.102.

4) Initiate the flow of fluid in accordance with the MANUFACTURER's instructions for use.

5) Set the test IRRIGATION pressure to 0 mmHg (0 kPa) or lowest setting and record pressure meter reading after 5 s.

6) Increase the test pressure values by 20 mmHg (2,7 kPa).

7) Wait for 5 s and record pressure meter reading.

8) Repeat step 6 and 7 for test pressure setting in 20 mmHg (2,7 kPa) increments until the maximum pressure setting is reached.

9) Repeat the readings used in steps 6, 7 and 8 as the pressure is decreased and wait for 5 s and record the pressure meter reading at each point.

NOTE This may involve reconnection of the IRRIGATION tubing for the decreasing measurements.

10) Confirm that all the readings are within the stated range.